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REMARKS

Status of the Claims

1-35 are pending herein. Claims 14-19 and 21-32 and 34 are withdrawn from consideration. Claims 1-13, 20, 33 and 35 are under examination.

Claim 33, previously dependent upon claims 22-25, has been amended to incorporate the limitations of claim 22 (the base independent claim). The base dependent claims (23-25) have been introduced as new claims 44-46.

Support for new claims 36- 46, which also depend from claim 33, can be found in original claims 2, 3, 7-9, 11-13.

Support for a microparticle that is formed in the absence of a polypeptide-containing molecule (claim 1) can be found, for instance, in Example 1.

Support for microparticles that do not contain entrapped or encapsulated polypeptide-containing molecules in new claim 47 can be found, for example, on page 23, lines 13-21, where it is noted that the microparticles may (and thus may not) have entrapped or encapsulated macromolecules, which include additional polypeptide-containing molecules. See also, Example 1, wherein microparticles are formed in the absence of polypeptide-containing molecules and therefore do not contain entrapped or encapsulated polypeptide-containing molecules. Support for the remainder of new claim 47 can be found in original claim 1.

Rejection of Claims 1-5, 7, and 10 under 35 USC §102(b)--Soriano

Claims 1-5, 7, and 10 are rejected under 35 USC §102(b) as allegedly being anticipated by I. Soriano et al., *Drug Development and Industrial Pharmacy*, 21(5), 549-558 (1995) ("Soriano"). Applicant respectfully traverses this rejection and its supporting remarks.

Moreover, the Examiner's rejection, which is based on the argument that, although Soriano describes encapsulation, at least some protein will inherently be adsorbed on the microparticle surface, is moot in view of the above amendment to claim 1 (see also new claim 47).

More particularly, for a reference to anticipate a claim it must disclose each an every element of the claim. See MPEP 2131 and cases cited therein, especially *Richardson v. Suzuki*

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Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (CCPA 1978).

The microparticles of claim 1 are formed in the absence of a polypeptide-containing molecule, and the microparticles of claim 47 do not contain entrapped or encapsulated polypeptide-containing molecules. Soriano, on the other hand, describes a method in which microparticles are prepared using the double emulsion technique wherein BSA is included in the first water phase, resulting in microparticles in which at least a fraction of the BSA is entrapped/encapsulated. See, e.g., Soriano Abstract, and p. 551 under "Microsphere preparation".

Thus, claims 1 and 47 (as well as claims 2-5, 7, and 10 depending from claim 1) are neither anticipated by nor obvious over Soriano.

Accordingly, reconsideration and withdrawal of this rejection are therefore requested.

Rejection of Claims 1-7, 10-12 and 35 under 35 USC §102(b)—O'Hagan

Claims 1-7, 10-12 and 35 are rejected under 35 USC §102(b) as allegedly being anticipated by O'Hagan et al. WO 94/27718 ("O'Hagan"). Applicant respectfully traverses this rejection and its supporting remarks.

Moreover, the Examiner's rejection, which is based on the argument that, although O'Hagan describes encapsulation, at least some protein will inherently be adsorbed on the microparticle surface, is moot in view of the above amendment to claim 1 (see also new claim 47).

More particularly, the microparticles of claim 1 are formed in the absence of a polypeptide-containing molecule, and the microparticles of claim 47 do not contain entrapped or encapsulated polypeptide-containing molecules. In contrast, as recognized by the Examiner (and analogous to Soriano), O'Hagan describes a method in which microparticles are prepared using a double emulsion technique wherein a bioactive material to be entrapped/encapsulated (e.g., an antigen) is included in the first water phase, ultimately resulting in microparticles with entrapped/encapsulated bioactive material. See, e.g., p. 7, lines 1-3 and page 8, lines 1-20.

Thus, claims 1 and 47 (as well as claims 2-7, 10-12 and 35 depending from claim 1) are neither anticipated by nor obvious over Soriano.

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Accordingly, reconsideration and withdrawal of this rejection are therefore requested.

Claim Rejections under 35 USC §103(a)

Claim 13 is rejected under 35 USC §103(a) as unpatentable over O'Hagan in view of Krieg et al. US 6,207,646 (Krieg).

Claims 8 and 9 are rejected under 35 USC §103(a) as unpatentable over O'Hagan in view of Pizza et al., *Science*, 287 (2000) 1816-1820 ("Pizza") and in light of WO 2004/032958.

Claim 20 is rejected under 35 USC §103(a) as unpatentable over O'Hagan in view of Constantino et al., *Vaccine*, 17 (1999) 1251-1263 ("Constantino").

Applicant respectfully traverses these rejections and their supporting remarks.

Moreover, for a proper obviousness rejection, the differences between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. §103.

In view of the above amendment to independent claim 1, this claim and all claims depending therefrom, including claims 13, 8, 9 and 20, are neither anticipated by nor obvious in view of O'Hagan. More particularly, O'Hagan describes a method in which microparticles are prepared using a double emulsion technique wherein a bioactive material to be entrapped/encapsulated (e.g., an antigen) is included in the first water phase, ultimately resulting in microparticles with entrapped/encapsulated bioactive material. Claim 1, on the other hand, is directed to a microparticle composition comprising microparticles, which are formed in the absence of a polypeptide-containing molecule (e.g., an antigen). Thus, claim 1 is neither anticipated by nor obvious in view of O'Hagan.

Krieg, Pizza and Constantino, which are cited as allegedly disclosing various features of the dependent claims, do not make up for the above-noted deficiencies in O'Hagan.

Withdrawal of the rejection of claims 13, 8, 9 and 20 under 35 USC §103 are respectfully requested.

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Claim Objection

Claim 33 has been considered but is objected to for depending from a withdrawn claim (i.e., dependent claims 22-25). Claim 33 has been amended to incorporate the limitations of claim 22 (the base independent claim). The base dependent claims (23-25) have been introduced as new claims 44-46. New claims 36-43 have also been added, which depend from claim 33. It is believed that claims 33 and 36-46 are now in condition for allowance.

CONCLUSION

It is respectfully submitted that all elected claims are in condition for allowance. Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicants' attorney at (703) 433-0510 in order that any outstanding issues be resolved.

CORRESPONDENCE


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